Chapter 05

PREMARKET NOTIFICATION
510(K) Summary

OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name:

JIANGMEN CITY XINHUI BAISHENG MEDICAL EQUIPMENT CO.,LTD

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Contact:	Mr. Chen Xi
E-mail:	renzheng@bs0750.com
Date	June 1, 2008

2.0 Proprietary Name: OBS Disposable Electrosurgical Pencils

Model: OBS-Db, OBS-Dr, OBS-Df

Common Name : Electrosurgical Pencil

Classification Name: Electrosurgical, cutting & coagulation & accessories

Classification: Class II

Product Code: GEI

3.0 Predicate Device Information:

1) SHINING WORLD HELTH CARE CO.,LTD

Company Name: SHINING WORLD HELTH CARE CO.,LTD

Address: 6F, No.8, Lane 7, Wu-Chun Road, Wu-Ku Industrial Park, Taipei, China(Taiwan)

Proprietary Name: SHINMED various models of electro-surgical pencils model : SW12200,SW12202, SW12300

It's 510(K) number is K033027

2) Unimed Surgical Products, Inc.
Company Name: Unimed Surgical Products, Inc.
Address: 10401 Belcher Road Largo, Florida 33777
Proprietary Name: Disposable Hand and Foot-Switching Pencil
It's 510(K) number is K993647
3) Tecno Instruments(PVT) Ltd
Company Name: Tecno Instruments(PVT) Ltd
Address: 316-C Small Industrial Estate Sialkot-51340 Pakistan
Proprietary Name: Tecno Disposable Fingerswitch Pencil
Model: 150-100
It's 510(K) number is K002257

4.0 Device Description

The OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df are used for the cutting and coagulation of soft tissue and have a connector attached to a 3M conductive cable and are designed for use with 510K-clearance generator. The connector or plug fits into the mono-polar side of a 510K-clearance generator. The handpieces (OBS-Db or OBS-Dr) are made of plastic with two buttons or a rocker switch toward the distal part of the pencil in the case of the hand-controlled pencils, while the foot-controlled pencils(OBS-Df) that is activated by a monopolar footswitch connected to the generator (the footswitch is an accessory of the generator). One button or switch is to control the CUT mode of the ESU while the other controls the COAG mode.

5.0 Indications for Use:

The OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df are used for cutting and coagulation to remove tissue and control bleeding by using high frequency current during electrosurgical surgery with a 510k-clearance ESU generator. The device is disposable and supplied sterile with an electrode tip.

6.0 Comparison to Predicate Devices

OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df, have been carefully compared to legally marketed devices with respect to intended use, appearance, essential components, materials and performance specifications. They are similar in intended use, appearance, essential components, materials and performance specifications. Although they may differ from the predicate devices in color and size, it won't affect safety and effectiveness of subject devices. In addition, performance and safety testing have been done to validate the performance and safety of the device.

7.0 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as below:

Electrical safety test, Mechanical performance test, sterile test, Biocompatibility test and EO Residue Test have been done to demonstrate the safety and performance of subject devices. Tests was conducted in accordance with the "510(k) Guidance Document for General Surgical Electrosurgical Devices", which outlines safety and performance requirements.

Tests were conducted on the OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df as per the requirements of IEC60601-1:1988 , IEC60601-2-2:2006, ANSI/AAMI/ISO10993-5:1999 , ANSI/AAMI/ISO10993-10:2002 ,ANSI/AAMI/ISO10993-7:1995, ANSI/AAMI/ISO11135-1:2007 and ANSI/AAMI/ISO11737-1:2006,ANSI/AAMI/ISO11737-2: 1998., USP 31:2008, <71>, BS EN ISO11607-1:2006, ISO 15223,ASTM F1980-07. None of the test demonstrated and design characteristics that violated the requirements of the above mentioned standards or resulted in any safety hazards.

8.0 Conclusions:

The comparison and validation results presented in this 510k notification to the FDA show that the OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df are substantially equivalent to predicated devices and is safe and effective in their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Jiangmen City Xinhui BaiSheng Medical Equipment Co., Ltd.
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

DEC - 1 2009

Re: K092634
Trade/Device Name: OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: November 13, 2009
Received: November 16, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 04

PREMARKET NOTIFICATION

Indications for Use

510(k) Number (if known):

Device Name: OBS Disposable Electrosurgical Pencils,
models: OBS-Db, OBS-Dr, OBS-Df

Indications For Use:

The OBS Disposable Electrosurgical Pencils, models: OBS-Db, OBS-Dr, OBS-Df are used for cutting and coagulation to remove tissue and control bleeding by using high frequency current during electrosurgical surgery with a 510k-clearance ESU generator. The device is disposable and supplied sterile with an electrode tip.

Prescription Use ___√___ **AND/OR Over-The-Counter Use**_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092634